REMARKS

Claims 34 to 38 remain in the application; claims 29 to 33 stand withdrawn and are canceled hereby. Applicants note appreciatively that the Examiner has withdrawn rejections based on references Sisley et al, Wilson et al and Butler et al.

The Drawings are objected to as failing to show the limitation in claim 35 that the cross-sectional shapes of the first and second proximal end regions are circular". Claims 35 and 36 are rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement by having support in the Specification or Figures for the different shapes between cross-sectional shapes of first and second intermediate sections being semicircular and then the cross-sectional shapes changing to circular in the cross-sectional shapes of the first and second proximal end regions.

The Brief Description of the Drawings is amended at paragraph [0014] to describe Fig. 2 as being a cross-section taken along lines 2-2 of both Figs. 1 and 7, thus meeting the requirement of showing the intermediate cross-section being semi-circular, while Fig. 8 shows the cross-section of the proximal ends of the catheter lumens being circular. Figure 8 is described in the Specification at paragraphs [0020] and [0042] as amended hereby. Figure 7 is amended to indicate location 2-2 wherefrom Figure 2 is taken. Thus, both the drawing objection and the rejection under §112 are obviated.

Claim 34 is amended to include the limitation that the site of releasable attachment of the hub to the catheter proximal portions is selectable by the practitioner and is attachable after subcutaneous tunneling has been completed. Support is found in paragraphs [0008] and [0057] of the Specification.

Claims 34 to 37 stand rejected under 35 USC §103(a) as being unpatentable over Hobbs et al (U.S. Patent No. 7,347,852) in view of Bierman et al (U.S. Patent No. 6,663,600). Claims 34 to 37 stand rejected under 35 USC §103(a) as being unpatentable over Ash et al (U.S. Patent No. 5,947,953) in view of Bierman et al (U.S. Patent No. 6,663,600). Claim 38 stands rejected under 35 USC §103(a) as being unpatentable over Hobbs et al and Ash et al in view of Bierman et al and Cazal (U.S. Patent No. 5,800,414). Claims 34 to 38 also stand rejected under "nonstatutory obviousness-type double patenting" in view of Serial No. 10/974,267.

In the presently claimed invention, the hub member is easily securable to the catheters by snap fit around continuing lengths of the proximal portions of the catheter so that the proximal catheter ends extend beyond the hub for attachment to fittings and, preferably, extension tubes. More importantly, the hub's site is optimally selectable by the practitioner after catheter implantation and subcutaneous tunneling of the catheter proximal end portions, who may have to trim the length of the catheter tubes rather than rely on an immediately available extensive inventory of catheter lengths needed to address needs of different patients. Further, the hub member is releasable from the catheter should it become necessary to repair the catheter: the present invention also provides for repair of catheters that have already been implanted into a patient, without removing a damaged catheter from the patient and re-implanting a new one, causing accompanying distress and risk to the patient. Reference is made to the Specification at paragraphs [0006] to [0008] and [0057] and [0059]. Thus, the presently claimed invention is a greatly advantageous breakthrough in catheter implantation and repair procedures.

Reference Hobbs et al sets forth a multiple-tube catheter assembly such as for hemodialysis, wherein the distal ends are separated from each other, and the proximal end portions are also separate from each other, and wherein intermediate portions thereof are removably

attached to each other using a removable wire or wires (or thread or sutures) threading together the two tubes. Proximally of the intermediate portions, a flexible separating prong holds the tubes apart to further assure that the catheter "cannot be moved." The wire or wires are said to be removed during removal of the individual catheter tubes from the patient. No hub member is disclosed, releasably attachable or not. Nor is the site of the catheter-to-catheter attachment selectable in any way by the practitioner, but is fixed at the factory.

Reference Bierman et al sets forth an anchoring system for securing a dialysis catheter to a patient, and comprising an anchor pad and a retainer where the anchor pad includes an adhesive bottom surface to be adhered to the patient's skin. The retainer is a clamp having a cover and a base hingedly joined and latchable in a closed position, that clamps about a catheter assembly as shown in Figures 14 to 16 thereof which show that the catheter assembly is clamped at the Y-site 112 of the proximal branches 114,116 with the main catheter 118. The retainer is stated to inhibit longitudinal movement of the catheter once clamped therearound. Y-site 112 is described in the reference at column 3, lines 17 to 33; column 6, lines 1 to 13; from column 10 line 66 to column 13 , line 4; and column 16, lines 30 to 65. At column 6, lines 11 to 13, is stated that the Y-site 112 may also include "a generally triangular plastic housing within which the branching of the lumens takes place." It would be generally understood by the skilled artisan that such a generally triangular plastic housing at the proximal branches of a catheter would be a hub. There is no disclosure in the reference that the plastic housing (or hub) is releasably attachable to the catheter at the proximal branching junction. Nor is the site of the Y-site 112 disclosed to be selectable by the practitioner.

Reference Ash et al has been discussed and distinguished in the previous Responses.

Reference Cazal sets forth a catheter having two lumens separated by an internal passageway 4 and being splittably joined to each other by easily splittable "surface material lines" along the outer surface adjacent the internal passageway 4, which is oval-shaped. To prevent further splitting beyond the proximal end portions, an amount of adhesive 14 is placed at the junction of the proximal ends with the remainder of the catheter; alternatively, an amount of adhesive 20 is placed at the junction to also affix an end of a tube 18 for establishing fluid communication of the tube's passageway 19 with the internal passageway 4.

Regarding claim 34, the Office Action characterizes reference Hobbs et al as disclosing "a hub 16 attached [sic: to] the first and second proximal end region of the first and second catheter [sic: catheters]" and that "the proximal end region/portion of catheter tubes 12 and 14 extend through the hub 16 . . ." Applicants respectfully traverse this characterization. Prong 16 is not a hub, and the catheter tube portions do not extend through it, all as would be understood by the artisan of routine skill in the art. Further, the site of prong 16 is not selectable by the practitioner nor is the prong attachable by the practitioner after catheter implantation and subcutaneous tunneling.

The Office Action characterizes reference Bierman et al as disclosing "a catheter device 8 with a separate hub 20." While component 8 is a catheter device (shown in dashed lines) only seen in Figures 14 to 16, component 20 is a retainer of an anchoring device 10, and is <u>not</u> a component of the catheter device to the extent relevant to the present claims. Furthermore, the Office Action on page 4, third paragraph, as best understood by Applicants, asserts that Bierman et al teaches a "releasably [sic: releasably attachable] hub" that "attaches or releases the hub to the tubes and the patient . . .". Applicants respectfully traverse this characterization of the reference. Catheter device 8 includes a Y-site 112 which optionally can comprise a plastic housing (or hub) (also

shown in dashed lines), as understood by the artisan of routine skill. Component 20 does not become a hub simply because it is releasably attachable about a catheter Y-site.

Further, if the skilled artisan were to desire to combine references Hobbs et al and Bierman et al, the result would be a catheter assembly releasably clampable by an anchoring device to anchor the catheter assembly to the skin of the patient to prevent catheter movement. The artisan would not modify Hobbs et al to replace its joining of the separate catheter tubes by threading them by wire(s), by an anchoring device 20, since such combination would clearly be against the express teachings of Hobbs et al. Even if made, the combination would not result in a hub attachable by the practitioner after catheter implantation and subcutaneous tunneling, nor at a site selected by the practitioner.

Claims 35 to 37 depend from claim 34, which is believed to patentably distinguish over the reference, and therefore, claims 35 to 37 are believed patentable.

With respect to the rejection of claims 34 to 37 over Ash et al in view of Bierman et al, Ash et al does not disclose a hub releasably attachable to the catheter nor along continuing lengths of proximal portions thereof, nor attachable after catheter implantation and subcutaneous tunneling by the practitioner, nor at a site selected by the practitioner; the hub is affixed to join catheter lumen ends to extension tube ends at the factory. Bierman et al fails to disclose these limitations, as well, and the combination cannot yield the present invention. Applicants traverse the rejection.

With respect to the rejection of claim 38 over Hobbs and Ash et al in view of Bierman et al and Cazal, Cazal does not teach adhesive to be splittable but instead expressly teaches that a drop of adhesive be placed at the end of already split proximal ends to prevent further splitting. Applicants traverse the rejection.

Claims 34 to 38 stand rejected for "nonstatutory obviousness-type double patenting" in view of the claims of pending but later-filed continuation-in-part application Serial No. 10/974,267. The present rejection is only provisional, since the present application has a filing date earlier than the other application and once all other rejections of the present claims is overcome, the double patenting is required to be withdrawn and the present application issue.

The claims are believed to distinguish patentably over the prior art, and allowance thereof is respectfully urged. No new matter has been entered hereby. If any additional fees are due, please charge same to Deposit Account No. 50-2434.

Respectfully Submitted,

J. Daniel Raulerson et al

March 24, 2009
Date

/Anton P. Ness/
By: Anton P. Ness
Reg. No. 28,453
Fox Rothschild LLP
10 Sentry Parkway, Suite 200
P.O. Box 3001
Blue Bell, PA 19422-3001
Telephone: 610-397-7984
Facsimile: 610-397-0450
E-Mail: aness@foxrothschild.com
Customer No. 33941